



Clue Receives FDA Clearance For Clue Birth Control, A Forthcoming Feature Of The Clue App That Uses Menstrual Data To Predict High and Low Risk Days

Backed by a full-scale clinical trial and powered by personalized data, Clue Birth Control offers a brand new form of all-digital contraception

BERLIN, GERMANY: 1ST MARCH, 2021 - Clue (www.helloclue.com), the science-backed female health app and leader in femtech, relied upon by 13 million people in over 190 countries, today announces it has received FDA clearance for Clue Birth Control, an all-digital form of contraception that uses period tracking data to allow women to monitor their fertility and prevent pregnancy. Clue Birth Control is [92% effective with typical use and 97% effective with perfect use](#).

Clue Birth Control algorithmically combines menstrual cycle data with a mathematical model to predict which days are high or low risk for pregnancy. After consulting Clue Birth Control, users can adapt their behaviors as necessary, for example by using condoms or avoiding sex that may result in pregnancy when the app indicates high risk.

Clue Birth Control will be available as a feature within the Clue app for eligible US-based users in 2021. Further countries will follow subject to the relevant regulatory approvals, as the contraceptive feature is a regulated medical device.

Clue Birth Control doesn't require users to track anything other than their period start dates, and its smart technology estimates a more accurate high risk window than traditional methods based only on period data. As the algorithm learns about a woman's cycle over time, the predictions become more personalized, and the high risk window estimated to contain ovulation can become shorter. The fact that no daily temperature measurements, other clinical observations or hardware are required is a major innovation in user-friendliness as compared to other fertility awareness-based methods of contraception.

To coincide with Clue's new reality as a regulated medical device company, there is a strengthening of the company's senior team, with founder Ida Tin moving to the role of Chairwoman of the Board, and the appointment of Audrey Tsang (formerly Clue's Chief Product Officer) and Carrie Walter (formerly Clue's General Counsel) as co-CEOs.

In her prior role as General Counsel, Carrie Walter, who joined Clue from Freshfields' international regulatory practice, was responsible for Clue's FDA application and has overseen the company's transition to a regulated company. Meanwhile, Audrey Tsang, who has led product strategy for global brands at scale, including at Pinterest and Yelp, led the development of the Clue Birth

Control feature as part of her responsibility for Clue's overall product portfolio as Clue's Chief Product Officer. Now that Clue is evolving from a health and lifestyle mobile app into a regulated, medical device-grade mobile app, together as Clue's new Co-CEOs, Carrie and Audrey will focus on bringing accessible birth control to many more people around the world. At the same time, Clue will continue to evolve as the trusted female health companion that already brings data-driven insights and science-backed information to millions at every stage of their reproductive lives.

What It Means To Be FDA-cleared As A Medical Device

Clue Birth Control is designed for contraception, and has been tested in a rigorous clinical trial for that purpose. In order to obtain FDA clearance to offer this feature, the US regulator examined not just the clinical trial, but subjected the entire app as well as Clue's software development processes to extensive scrutiny. Clue had to satisfy the FDA that its science is sound, and that its way of working is up to the standards expected of a medical device manufacturer.

There are a multitude of period tracking apps on the market that claim to provide fertility predictions. When people rely on such unregulated apps to prevent pregnancy, they are likely unaware of how big a risk they are taking. The predictive algorithms such apps use may have little basis in science, or the predictions may not be generalizable to a particular type of user, and the apps themselves have probably never been independently audited for quality. Birth control products are highly regulated for a reason: an unintended pregnancy can be devastating, and people have to make careful, informed choices that suit their needs. A free app from an unregulated manufacturer should never be relied on for effective birth control.

Efficacy Backed By Scientific Research

According to a year-long, full-scale and representative [independent clinical trial](#) of over 700 women conducted by researchers at the Institute for Reproductive Health (IRH) at Georgetown University, Clue Birth Control's algorithm is 92% effective with typical use (how an average person would use it) and 97% effective with perfect use (when used exactly as directed). For comparison, the combined oral contraceptive pill is 93% effective with typical use and 99.7% effective with perfect use. Condoms alone are 87% effective with typical use and 98% effective with perfect use according to the [Guttmacher Institute](#).

The IRH researchers collaborated with U.S.-based Cycle Technologies Inc., who developed an app called Dynamic Optimal Timing (DOT) to conduct the clinical trial. When Clue was looking for a better fertility awareness solution to implement as a feature for the Clue app, it acquired the DOT algorithm and implemented the DOT app's functionality in the Clue Birth Control feature.

Clue At The Forefront Of Female Health

According to the Centers for Disease Control and Prevention (CDC), [in the United States 45% of pregnancies in 2011 were unintended](#), with most resulting from not using contraception or not using it consistently or correctly. In addition, a recent 2019 study showed that 73.2% of women

who use hormonal contraception discontinued or switched contraception due to side effects¹. Feedback from Clue's own user base also specified the desire for a tech-driven birth control option that was both side effect and hormone-free, easy-to-use, and backed by science.

Ida Tin, Clue's Founder, comments: "We could see that the contraceptive options out there simply weren't good enough. We wanted to utilize our strengths in cycle science and data science to upgrade traditional fertility awareness-based contraceptive methods and create a smart version, easy to use, powered by the technology in our pockets. We wanted a trustworthy and reliable alternative for women, one that is based on their own personal data, effective, has no side effects, and is hormone-free. We're excited that we have FDA clearance for Clue Birth Control, an innovation in natural pregnancy prevention which we believe will prove a better and more convenient method for many people's needs and lifestyles."

Lynae Brayboy, MD, FACOG, Clue's Chief Medical Officer, is heading up Clue Birth Control. She comments: "Hormonal birth control has done wonders to improve the lives of people with periods worldwide and we are supportive of those who benefit from it. However, the lack of effective and convenient alternatives for women, the added economic and healthcare challenges of the SARS-CoV-2 pandemic, and the recent July 2020 United States Supreme Court ruling that allows employers to opt-out of birth control coverage, will only complicate an already dire situation for women. Clue Birth Control is a practical digital fertility awareness-based method that is accessible, affordable and portable because users can access it on their phone in the privacy of their homes. It also has the added benefit of being personalized so that women can understand their own menstrual cycles which has implications for their overall health"

Who Is Clue Birth Control For?

To ensure efficacy, accuracy, and safety, there are restrictions on who can use Clue Birth Control. Because this is a predictive feature, Clue Birth Control works best for those who have relatively predictable periods. Before accessing the feature, potential users will undergo a detailed in-app onboarding process which determines whether or not they meet our eligibility criteria.

Clue Birth Control works for users who are 18 to 45 years old and who:

1. Are able to track their period, and check the app each day they have sex
2. Are prepared to use a condom or avoid sex that may result in pregnancy on high-risk days
3. Have cycles that are 20 to 40 days long
4. Have cycles that varied by 9 days or less over the last 12 cycles
5. Have had 3 cycles (4 periods) since stopping hormonal birth control or being pregnant

¹ Simmons, R. G. et al.: Predictors of contraceptive switching and discontinuation within the first 6 months of use among Highly Effective Reversible Contraceptive Initiative Salt Lake study participants. American Journal of Obstetrics and Gynecology. 2019; 220, 376.e1-376.e12

People who are currently taking hormonal birth control, have recently stopped, or have recently been pregnant or breastfeeding, will need to wait until their cycles have returned to their previous menstrual cycle patterns before starting Clue Birth Control.

Clue Birth Control will not be suitable for everyone. It does not protect against sexually transmitted infections (STIs). And, while no method of contraceptive is 100% effective, there are more effective contraceptive options (e.g. intrauterine devices (IUDs), which do not require user participation). For many people, protection from STIs and a “set and forget” method of birth control, will be paramount at some stage in their lives.

A Management Team For A Regulated Medical Product

Clue founder Ida Tin will be moving to the position of company Chairwoman, with Audrey Tsang (Clue Chief Product Officer since 2018) and Carrie Walter (Clue General Counsel since 2019) becoming co-CEOs.

These moves follow the appointment of Lynae Brayboy, MD, FACOG as Chief Medical Officer in Summer 2020, and further strengthen the company’s leadership as Clue enters the regulated medical device sector, and continues to develop more features to address the unmet requirements of women and people with cycles at different stages of their lives.

Ida Tin comments on the moves: “This new senior team formalizes Clue’s growth from category-creating startup to approved medical device company, and brings a wealth of necessary business, regulatory, and clinical expertise. I am proud of what Clue has achieved, and look forward to my new role on the company’s Board and watching how this brilliant team will take us to the next level of consumer femtech.”

About Clue

Berlin-based Clue was founded in 2012 by Danish entrepreneur, Ida Tin. Built by a dedicated team of developers and data scientists, Clue has built advanced algorithms to detect users’ unique patterns in the cycle-related symptoms they track. Clue is then able to provide personalized predictions based on the individual user’s data.

Clue has forged research collaborations with The Kinsey Institute, Stanford University, Columbia University, the University of Washington and the University of Oxford. Each research collaborator is carefully vetted and selected by Clue to answer specific research questions of a non-commercial nature.

Clue is available in 15 languages (English, Spanish, Portuguese, German, French, Italian, Danish, Russian, Chinese (traditional and simplified), Japanese, Polish, Hindi, Korean and Turkish) and is on iOS, Android and Apple Watch. Clue users can also link their account to Apple’s HealthKit, enabling them to push the following data to Apple’s Health app: basal body temperature, cervical mucus quality, menstruation, ovulation test results, sexual activity, spotting, and weight.

To date, Clue has raised over \$30 million. The company’s investors include Nokia Growth Partners (NGP), Union Square Ventures (USV), Mosaic Ventures, and FJ Labs, as well as top startup entrepreneurs from Spotify, Dropbox, SoundCloud and Toca Boca.